APPENDIX

Summary of Alleged Misstatements

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]

1	142-144	**Speaker(s)**: FibroGen, Neff (CEO), Yu (CMO)
		Date: December20, 2018
		Occasion: FibroGen Press Release announcing "Positive Topline Results from Three Global Phase 3 Trials of Roxadustat"
		(Exhibit E)
			1. Yu: "We are excited to have ***achieved superiority in efficacy not only against placebo but also over epoetin alfa in our studies… [t]hese results support [R]oxadustat's potential to bring clinical benefit over current standard of care***, such as reducing blood transfusion risk in patients on dialysis and those not on dialysis, and to improve patient access to anemia therapy with a new convenient oral therapeutic."	• Efficacy Statement	• Falsity Not Pled with Particularity
					• Opinion Statement
					• Forward-Looking Statement ("potential")[4]
					  ○ Identified As Forward-Looking (Ex. E at 6) & Adequate Cautionary Language (Ex. A at 85, 103-04)
					  ○ No Allegations of Actual Knowledge of Falsity

2			2. Neff: "This is the first well-controlled CKD anemia program that has shown ***improved efficacy in incident and stable dialysis patients relative to ESA standard ofcare therapy***. Each of the three studies had a pre-specified primary efficacy endpoint for meeting U.S. regulatory requirements and another pre-specified primary	• Efficacy Statement	• Falsity Not Pled with Particularity • Opinion Statement

[1] To provide the Court with the context surrounding the challenged statements, Defendants have taken the Appendix attached to Plaintiffs' Consolidated Class Action Complaint and added relevant text before and/or after each challenged statement. Plaintiffs' Appendix included both emphasized and non-emphasized portions and it is not clear which portions they are challenging. In Defendants' Appendix, the underlined portion of each statement indicates the language found in Plaintiffs' Appendix and the bolding appears as it does in Plaintiffs' Appendix. The non-emphasized text has been added by Defendants for context.

[2] For ease of reference, Defendants have identified statement categories, which track the categories identified in Defendants' Motion to Dismiss. The "Black Box" statements are discussed in Defendants' Motion to Dismiss, Part IV.A.1, the "Non-Inferiority Margin" statements are discussed in Part IV.A.2, the "Efficacy" Statements are discussed in Part IV.A.3, the "Safety Analysis" statements are discussed in IV.A.4. A number of these statements are also inactionable opinion, corporate optimism, or forward-looking statements discussed in Part IV.A.5 and IV.A.6. The "Miscellaneous" statements are not directly categorized in Defendants' Motion to Dismiss but are also inactionable for the reasons identified in the Column labeled "Reason Not Actionable," which tracks the arguments made in Defendants' Motion to Dismiss.

[3] All of the challenged statements are also not actionable as Plaintiffs fail to plead facts raising a strong inference of scienter as to any Defendant.

[4] Many of the challenged statements are mixed statements, both containing historical facts and forward-looking language or opinion, or corporate optimism. All arguments applicable to all portions of the lengthy statements that Plaintiffs challenge are addressed.

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
			efficacy endpoint for meeting EU regulatory requirements, which also served as a secondary efficacy endpoint for the U.S. Both the U.S. and EU primary efficacy endpoints were met in all three studies . . . a U.S. primary efficacy endpoint: . . . mean Hb [hemoglobin] change from baseline."		
3			3. Press Release: "***[I]n the pre-specified secondary efficacy analysis, Roxadustat-treated patients had a 33% reduction in the risk of blood transfusion compared to epoetin alfa*** (HR=0.67) in the time to first blood transfusion during treatment, p=0.0337."	• Efficacy Statement	• Falsity Not Pled with Particularity
4			4. Press Release: "***The preliminary safety analyses of each of these three individual studies show an overall safety profile consistent with the results observed in prior Roxadustat studies. The adverse events reported are consistent with those expected in these study populations with similar background diseases.*** . . . Results of the pooled safety analyses, including the major adverse cardiovascular events (MACE) for both NDD-CKD and DD-CKD in the global Phase 3 program is anticipated prior to U.S. NDA submission in the first half of 2019."	• Safety Analysis Statement	• Opinion Statement • Falsity Not Pled with Particularity
5	145-146	**Speaker(s)**: FibroGen, Neff (CEO),Yu (CMO) **Date**: February27, 2019 **Occasion**: 4Q and FY2018	5. Neff: "In these 5 U.S. ROW studies, we enrolled a total of 7,721 patients composed of 3,917 in dialysis and 3,804 in non-dialysis. All of these studies ***have positive top line results.*** We and our partners believe the results from these trials to ***support our NDA [to the FDA]*** as well as our marketing authorization application, or MAA, to the European Medicines Authority, or EMA. The fully adjudicated MACE results, including completing adjudication procedures to enable consistent safety assessment without bias, are to be included in our planned NDA to the FDA. Completion of the full adjudication procedures is on track for the second quarter of 2019.	• Efficacy Statement • Miscellaneous Statement	• Falsity Not Pled with Particularity • Forward-Looking Statement (NDA prospects) o Identified As Forward-Looking (Ex. G at 4) & Adequate Cautionary Language (Ex. H at 62, 82) o No Allegations of Actual Knowledge of Falsity • Opinion Statement

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
		Earnings Call **(Exhibit G)**	… At this point, ***based on our review of the data*** to date and our discussions with counterpart teams at AZ and Astellas and discussions with our partners' leadership ***there is a strong conviction to move ahead to file the NDA*** and MAA ***this year***."		
6			6. Yu: "First of all, these Phase III studies demonstrated roxadustat's efficacy. We met the primary efficacy end point in each of the 3 CKD non-dialysis studies, ANDES by FibroGen, OLYMPUS by AstraZeneca and ALPS by Astellas, by demonstrating superiority of roxadustat compared to placebo in the change in hemoglobin level from baseline, the hemoglobin averaged over weeks 28 to 52. In the Phase III dialysis studies, noninferiority criteria were met in primary end point comparing hemoglobin change in roxadustat-treated patients with those on EPO alfa, which is the current standard of care in dialysis and in CKD patients. And furthermore, ***superiority [to Epogen] was demonstrated in all 3 dialysis studies***… . . . Also, ***much clinical importance,*** roxadustat-treated patients had significant reduction in red blood cell transfusion risk, which was measured by time to first transfusion when compared to placebo in CKD non-dialysis studies. Moreover, in active control trial in SIERRAS study, our U.S. dialysis conversion study in which patients were randomized to receive Roxadustat or to continue stable maintenance dose of epoetin alfa, ***roxadustat was*** also ***shown to have a lower transfusion risk than ESA***. Other than the usual risks…red blood cell transfusion is known to reduce CKD patients' eligibility for kidney transplant …Kidney transplant is the preferred option for patients with end-stage kidney disease because of longer survival than chronic dialysis. This is why transfusion reduction is such a ***big deal*** and could be ***of great significance to CKD patients***."	• Efficacy Statement	• Forward-Looking Statement ("could be of great significance") o Identified As Forward-Looking (Ex. G at 4) & Adequate Cautionary Language (Ex. H at 62, 66, 82) o No Allegations of Actual Knowledge of Falsity • Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism

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7			7. Yu: "Turning to preliminary safety data. ***Results in individual studies are consistent with what one would expect in the study patient population***. The integrated full safety analyses are ongoing. The adjudicated MACE results are on track for the first the first half of 2019. ***Encouragedby the robust efficacy results, the preliminary safety data in individual Phase 3 studies and the ongoing pool efficacy and safety analyses***, we are working diligently with our partners, AstraZeneca in the preparation of NDA submission in the U.S. and with Astellas in the preparation for the MAA in Europe."	• Efficacy Statement • Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism
8	147-152	**Speaker(s)**: FibroGen, Neff (CEO),Yu (CMO) **Date**: May 9, 2019 **Occasion**: Press Release announcing "Positive Topline Results From Pooled Safety Analyses ofRoxadustat Global Phase 3 Program" (the "May 2019 Press Release") **(Exhibit I)**	8. Press Release: (i) "Based on the MACE safety data analyses of [DD], we believe there is ***no clinically meaningful difference in risk*** of MACE between Roxadustat and epoetin alfa" and "Based on the MACE safety analyses of [NDD], we believe there is ***no clinically meaningful difference in risk*** of MACE between Roxadustat and placebo"; and (ii) "Roxadustat demonstrated ***superiority*** to epoetin alfa ***in the time to first MACE+ in [incident dialysis patients].*** In the MACE analysis, there is ***a trend toward reduced [MACE] risk for patients on [R]oxadustat***, compared to epoetin alfa."	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement
9			9. Press Release: "Of note, multiple MACE and MACE+ analyses in NDD-CKD from the roxadustat global Phase 3program are being performed in intent-to-treat (ITT) analyses that demonstrated comparability ofroxadustat to placebo. ITT is among the several statistical methods that we will discuss with the FDA. ***In these analyses, Roxadustat was comparable based on a commonly applied non-inferiority margin of 1.3***."	• Non-Inferiority Margin Statement • Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement
10			10. Yu: "***We are particularly excited about the results indicating a reduction of risk of MACE+ events in incident dialysis patients*** and the additional potential clinical benefits of Roxadustat beyond anemia	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Statement of Corporate

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			correction, to include attenuation of renal function decline and improvement of quality of life in NDD-CKD patients. . . . Further analyses of overall safety is ongoing and will inform on the overall benefit risk."		• Optimism • Opinion Statement
11			11. Neff: "We are very pleased with what we believe are important positive results of MACE and MACE+ analyses in the dialysis-dependent, incident dialysis, and non-dialysis dependent CKD patients, supporting the safety of Roxadustat in CKD patients . . . Combined with the positive topline efficacy in hemoglobin (Hb) control in patients with or without concomitant inflammation, reduction of transfusion, and the encouraging results from the pooled analyses of Quality of Life and estimated glomerular filtration rate (eGFR) over time, ***these positive safety data give us confidence as we progress in preparation for the U.S NDA*** and the Marketing Authorization Application (MAA) for EMA."	• Safety Analysis Statement • Miscellaneous Statement	• Falsity Not Pled with Particularity • Forward-Looking Statement (NDA prospects) o Identified As Forward-Looking (Ex. I at 5) & Adequate Cautionary Language (Ex. H at 62, 66, 82) o No Allegations of Actual Knowledge of Falsity • Opinion Statement
12			12. Neff: "Combined with the positive topline efficacy in hemoglobin (Hb) control in patients with or without concomitant inflammation, ***reduction of transfusion, and the encouraging results from the pooled analyses of Quality of Life,*** and estimated glomerular filtration rate (eGFR) over time, these positive safety data give us confidence as we progress in preparation for the U.S NDA and the Marketing Authorization Application (MAA) for EMA."	• Efficacy Statement	• Falsity Not Pled with Particularity • Opinion Statement
13			13. Yu: "We are particularly excited about the results indicating a reduction of risk of MACE+ events in incident dialysis patients, and the additional potential clinical benefits of Roxadustat beyond anemia correction, to include attenuation of renal function decline and ***improvement of quality of life in NDD-CKD patients***," said K. Peony Yu, MD, Chief Medical Officer, FibroGen. As we accumulate a body of evidence of roxadustat efficacy and safety with these	• Efficacy Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism

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			adjudicated pooled analyses, we look forward to begin discussions with U.S. FDA on NDA submission. . . . In the pooled analyses from the three NDD studies, we observed statistically significant improvements from baseline to Week 12 in quality of life endpoints, including SF-36 Vitality subscale(p=0.0002), SF-36 Physical Functioning subscale (p=0.0369), FACT-AN Anemia subscale(p=0.0012), FACT-AN Total score (p=0.0056), and EQ-5D-SL VAS score (p=0.0005) when comparing roxadustat to placebo in CKD patients not on dialysis."		

14	153-161	**Speaker(s):**
		FibroGen, Neff (CEO),Yu (CMO)
		Date:
		May 9, 2019
		Occasion:Q1 2019 Earnings Call
		(Exhibit J)
			Analyst Question: "Tom and Peony, can you be very clear for us? I think there's some confusion around whether you are statistically noninferior in dialysis and nondialysis on the MACE analysis, which is what is required for FDA? Can you confirm that or discuss that? And if you can also give us the hazard ratios for dialysis and nondialysis on MACE, that would be very helpful. . ."
			14. Neff: "Okay. So Michael, there's 2 parts to this answer. One is that in the European market, we are doing MACE+, where we have a statistical noninferiority margin, a single margin identified, and we are noninferior in both measures. In the U.S., there are multiple noninferiority margins that are under discussion. These are reflecting the fact that was not incident dialysis and with the nondialysis-dependent CKD patients, we are essentially addressing new indications that have not been investigated previously. So that's incident dialysis and the CKD dialysis. In discussions with our partner, they are very mindful of the phrase totality of evidence. And so they encouraged the idea that we address this in the form of the evaluation of results versus MACE, where we did not see any clinically meaningful difference, ***means that [Roxadustat] met the safety standards that people were looking for and that's whypeople are moving forward***…Yes. I think ***the message there is we're***
				• Safety Analysis Statement	• Falsity Not Pled with Particularity
					• Forward-Looking Statement ("trending favorably")
					  ○ Identified As Forward-Looking (Ex. J at 4) & Adequate Cautionary Language (Ex. H at 62, 66, 67, 82)
					  ○ No Allegations of Actual Knowledge of Falsity
					• Opinion Statement
					• Statement of Corporate Optimism

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			trending favorably." *Id.* at 12.		
15			Analyst Question "So just kind of digging deeper and helping us kind of understand the totality of data. Different components, death, MI, stroke. On top of that, unstable angina leading to a hospitalization, heart failure. Can you confirm that all of these measures are trending in the right direction? Or maybe there are some that's not. Maybe can you comment on that? . . ." 15. Neff: "So with the MACE+ data, I believe we have numeric advantage in each category. So there's 5 categories. . . . ***Every one of [the MACE+ categories], we have a numeric advantage over ESA… Fewer events in Roxa versus ESA in deaths. Fewer events in Roxa versus ESA in myocardial infarction. Fewer strokes in Roxa than ESA. Fewer unstable angina hospitalizations. Fewer congestive heart failures resulting in hospitalizations***." *Id*. at 16.	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement
16			Analyst Question: "Okay. And then a question on the nondialysis MACE analyses. Did the event rate compare favorably to the comparator arm? And how -- in that analysis, how does it take into consideration the differences in the dropout rate?" 16. Yu: "So we have -- ***because our drug is so efficacious and so well tolerated, patients really like staying on our drug.*** . . . And even we did see a high -- a somewhat higher dropout rate in placebo-treated patients. However -- and to have some anticipation this could happen, we have collected safety data on patients during the post-treatment period. And that's why we are able to conduct the ITT analysis. And this will be -- of course, the final assessment in -- and the statistics will be discussed with the FDA. And I just wanted to share that in the nondialysis population, [ITT] is – will be considered a relatively conservative analysis. And ***the fact that*** we had ***-- we are able to show non-inferiority to placebo under such conditions*** really illustrates the strength of our drug's safety. And I wanted to also remind us that placebo is considered ***the gold standard***	• Efficacy Statement • Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement

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			for safety." *Id.* at 14.		
17			Analyst Question: "So to be very specific, in dialysis and nondialysis on MACE, are you trending the right way? Are you trending positive? What do you mean by not clinically meaningful differences?" Neff: "Yes. I think the message there is we're trending favorably. But at the same time, we have to yet agree with our regulator on specific analyses to be done. There are back and forth discussions. 17. Yu: "[M]ay I add to [that] question . . . ***[F]or us to state that we are superior in time to MACE+ analysis in incident dialysis, what I mean isthe upper bound of the 95% confidence interval is less than 1. And… when you compare the hazard between Roxadustat to that of epoetin alfa, we have a very significant p value***." *Id.* at 13.	• Safety Analysis Statement • Non-Inferiority Margin Statement	• Falsity Not Pled with Particularity • Opinion Statement
18			Analyst: "Provide us reassurance that the number of…deaths, MIs, and STROKES in the stable dialysis patients who were switched to Roxadustat, still favors Roxadustat. Because obviously, you don't have the same power or same apparent benefit in the pooled dialysis as you do in the incident." 18. Yu: "[W]hen we look at subgroup analysis of the – between incident dialysis versus the stable conversion dialysis, ***we are quite comfortable with the safety result when looking at MACE and MACE+***… even though I'm not giving you exact number of patients for each category, right, but I am willing to share with you that in the subgroup analysis, ***when we tested time to—for example, MACE+ and MACE, Roxadustat was at least non- inferior to epoetin alfa even in the conversion stable dialysis patients***. . . . we're at this -- we are still on the -- releasing the top line results. The fine granular geographic subgroup analysis and more detailed analysis are -- still needs to be conducted. But we'll plan to -- between now and NDA submission, it will be completed before then." *Id.* at 19.	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism

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19			Analyst: "Maybe just a follow-up. I think that your answer to the last question regarding the dialysis population was pretty clear. But in terms of the nondialysis comparison of roxa versus placebo, I guess, I'm still a little bit confused in terms of how the -- I understand you didn't have a prespecified comparison. You're looking at a number of different ways. But could you maybe just walk through how those event rates compare on MACE for roxa versus placebo across the different analyses? Were there -- did they all line up? Were they all favorable? Was there anything out of line? And then when you look at the separate studies, again, I remember back from the [Amanta] studies, they had one trial that they showed fewer events and one trial they actually had more events in the nondialysis setting. So again, was there consistency across the 3 studies that you pooled as well?" 19. Neff: "Yes. So Terence, we recognize that this is a terribly difficult area to state in a succinct manner for a call like this. Having said that in thinking about how to ***describe the situation most effectively***, we decided to describe the ITT results. This is MACE, MACE+, MACE CV, time to MACE+, time to MACE. So there's several different measures. And in each case, the result of the analysis was at a ***ratio below 1.3***, which is a standard noninferiority comparison in ITT. And so when I say below 1.3, I mean like 1.18 or 1.21 or 1.27 or 1.28. Not above 1.3, but below 1.3. And I know, speaking as someone involved in this partnership for a long time, that people in each of our partners' executive management group, great confidence and strength in seeing these results because these are -- even though these maybe aren't the measures that will ultimately be the ones that are evaluated, they are an ultimate safety evaluation standard ***the FDA usually asks*** for whether you pose it or not. So everybody felt like this is something that's very descriptive and very informative. I would hesitate to do anything else beyond talking about the ITT results because we do not have a specific agreement with FDA on method of analysis. And as such, it's a little presumptuous." *Id.* at 16-17.	• Non-Inferiority Margin Statement	• Falsity Not Pled with Particularity • Opinion Statement

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20			Analyst: "Okay. Okay. Now for the indication in the U.S., if we just think about DD and NDD for now, for the MACE status, now we can forget about the MACE+ situation. Just for the MACE measurement, have you reached a statistical noninferiority on -- against either placebo or EPO?" 20. Yu: "so whether you would reach statistically significant in noninferiority, it really depends on what the noninferiority margin is. And in Europe, we are more clear on the noninferiority margin, and we believe that we have achieved that. And for -- now for the incident dialysis, the nice thing about achieved superiority is that no matter what the noninferiority margin it is, once we can demonstrate superiority, we have already crossed it. And ***we are using the conventional standards of noninferiority, which is widely published for assessment of CKD anemia and have previously been used by [the FDA] for assessment of cardiovascular safety*** in similar types of composite endpoints …***that standard has been 1.3 for upper bound of 95% confidenceinterval. If we use that standard, the answer is yes, we have achieved non-inferiority."*** *Id.* at 20.	• Non-Inferiority Margin Statement • Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement

21			Analyst: "A couple of questions for me. First, based on this MACE data, how do we think of the label language if approved? Are we confident to avoid a black box?"
			
			21. Yu: "what FDA puts on the label is something that they – that we may not have much control over, except that we have developed that we'll target a certain label. And so we – FDA has advised that the evaluation of efficacy, primary efficacy, will be based on individual studies, and we have checked that box. And the evaluation of safety is FDA may – will look at various aspects of safety. And ***based on what we have seen, we are pretty comfortable with safety. This adjudicated composite safety endpoint was something that we have discussed with the FDA*** . . . But at the end, the assessment is -really depends on the medical reviewer at the FDA. And there will -- if there were an Advisory
				• Non-Inferiority Margin Statement
				• Safety Analysis Statement
				• Black Box Statement
					• Falsity Not Pled with Particularity
					• Forward-Looking Statement (NDA/label prospects)
					  ○ Identified As Forward-Looking (Ex. J at 4) & Adequate Cautionary Language (Ex. H at 62, 66, 67, 82)
					  ○ No Allegations of Actual Knowledge of Falsity
					• Opinion Statement
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			Committee, then there would be input from the Advisory Committee if the FDA chooses to." *Id.* at 22.		
22	136-138, 162, 149-151	**Speaker(s)**: FibroGen, Neff (CEO),Cotroneo (CFO) **Date**: May 9, 2019 **Occasion**:Q1 2019 Form 10-Q **(Exhibit L)**	22. 10-Q: "With the understanding that regulatory authorities will need to review the data and conduct their own analyses and evaluation of the overall benefit-risk profile of roxadustat, our NDA submission package to the FDA will be based on the totality of evidence of efficacy and safety. We have had extensive discussions with the FDA on the specific statistical standards for the various analyses and endpoints and we are planning to seek further input from the FDA on the content and format of our planned NDA submission package in an upcoming pre-NDA meeting to facilitate the FDA's review of the package. . . . For the U.S., where the focus will be on MACE, based on the collective results of the various MACE analyses, we believe there is ***no clinically meaningful difference in MACE risks between roxadustat and epoetin alfa***. . . . In the MACE analysis of this same subgroup [incident dialysis], there was a trend toward ***reduced risk of MACE for patients on roxadustat, compared to epoetinalfa***." . . . For the U.S., where the focus will be on MACE, based on the collective results of the various MACE analyses, webelieve there is ***no clinically meaningful difference in MACE safety between roxadustat and placebo in this same non-dialysis population***."	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement
23	163-166	**Speaker(s)**: FibroGen, Neff (CEO),Yu (CMO) **Date**: June	Analyst: "[W]hat were the results on top line and what we can expect in terms of a little more details as we proceed in the future." 23. Yu: "So we've recently reported exciting positive full adjudicated cardiovascular safety results from the largest Phase III CKD anemia program. We believe we have ***compelling evidence confirming [R]oxadustat's***	• Safety Analysis Statement • Efficacy Statement	• Falsity Not Pled with Particularity • Opinion Statement

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		12, 2019 **Occasion**: Goldman Sachs 40th Annual Global Healthcare Conference **(Exhibit M)**	***cardiovascular safety to support our regulatory filings***…For U.S., we believe ***our MACE results in dialysis and in non- dialysis also support the conclusion of no increased cardiovascular safety risk***. To further frame the safety result, along with efficacy together, in dialysis, I also want to emphasize ***[the] MACE+ superiority in [the] incident dialysis pool*** of over 1,500 patients. Lower MACE+ risk than EPO in incident dialysis may allow Roxadustat to become first-line therapy for patients starting dialysis and continuing long-term anemia treatment. Superiority in transfusions avoiding EPO hyporesponsiveness are important benefits too in this population. For nondialysis, we believe safety noninferiority against placebo in MACE and MACE+ coupled with efficacy benefits like ***transfusion reduction,*** attenuation of renal progression, measuring eGFR change and ***improvement in quality of life*** when treating patients with roxa may give us the opportunity to improve and expand anemia care in the very large CKD nondialysis patient population."		
24			Analyst: "Okay. Maybe on the market development side, with respect to the competitive landscape, there are various factors, such as biosimilars potentially launching in the U.S. on the EPO side at some point in the foreseeable future potentially. But in terms of other therapeutic modalities, are there anything -- is there anything out there that keeps you awake at night in terms of a competitive perspective outside of the EPO or biosimilars that you see coming on here that are on your radar screen with respect to competitive pressures?" 24. Neff: "[W]e're in a place now ***where we have safety data and efficacy data that's superior to [Epogen] in a U.S. setting***. So I think that situation and all the implications around it is being reevaluated a bit. I think we'll be watching with some interest whether any of the HIF companies can get enough momentum to sort of they'll -- fast follower-type companies. But as it relates to ESAs or PEG-ESAs, I'm not so sure we're	• Efficacy Statement • Non-Inferiority Margin Statement • Safety Analysis Statement • Black Box Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism

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			thinking that's a major competitive risk at this point. [Analyst: So you think primarily of the HIF, whether it's 2 alphas or other things like that, being relatively early stage in terms of the competitive landscape and not differentiated . . .] In the U.S., there are a couple of factors related to ***how we've differentiated ourselves*** and I think in one respect doing the work to do [a] placebo study in CKD ***and show that we are as safe as the placebo control arm is a very exciting place to be***. That took a lot of effort over a long period of time. And I know that FDA has expressed in various ways that they're very pleased with the progress over the years and what's gone on. And in the incident dialysis setting we also set out a thesis, 2012, 2013, that an incident dialysis comparison would be favorable to the roxa technology over EPO. And so we've ended up creating a pool of almost 1,600 patients in a incident dialysis setting where from the time a patient might initiate dialysis any time in the next 4 months they randomize to either roxa or EPO, then we study them all the way through and ***we've had outstanding results in this area.*** We think it's the most fair comparison of [Epogen] to Roxa. ***We think it opens the door to Roxa being recommended as a first medicine*** both in the U.S. and in China. And so I think that we'll see how it develops. You can never be sure until you get there, but ***it looks very, very promising at this point."*** "I think a key goal in the U.S. was— with CKD population, a placebo study was to show non-inferior to placebo, to show that there isn't any incremental risk measure so that it ***opens the doorto the logic [that Roxadustat] shouldn't have a 'Black Box' for placebo. Therefore, Roxa should not have a 'Black Box'*** and go from there in dealing withdialysis. ***And it's turned out as we hoped for."***		
25	167-168,	**Speaker(s)**: FibroGen, Neff	25. Neff: "We are pleased to report that in our in our pre-NDA meeting with the FDA regarding Roxadustat, we reached an agreement with the [FDA] on the content	• Miscellaneous Statement	• Falsity Not Pled with Particularity

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
	170	(CEO),Yu (CMO)	of the NDA including the cardiovascular safety analysis." *Id.* at 4.		
26		**Date**: August 8, 2019 **Occasion**:Q2 2019 Earnings Call **(Exhibit N)**	26. Yu: "As stated by our US partner AstraZeneca, our ***Phase 3 results confirmed the cardiovascular safety of [R]oxadustat***. Together with our partners, AstraZeneca and Astellas, we recently had a very good pre-NDA meeting with the FDA on roxadustat. We reached an agreement with the FDA on our proposed pooled MACE analysis in dialysis and in nondialysis. We are pleased with the agreement for nondialysis as it includes an approach to account for the differential dropout between roxadustat and placebo. With agreement on NDA content and format, we are moving as quickly as we can for a submission. We do have a large submission, at this time, we are targeting October of this year." *Id.* at 5. "So we are ***very pleased with the agreement [with the FDA] on the primary safety analysis ofour primary cardiovascular safety endpoint in NDD***." *Id.* at 12.	• Safety Analysis Statement • Miscellaneous Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism (because of the "very pleased")
27			Analyst: "what were the 2 or 3 most important things that you guys discussed with the FDA or topics or key issues regarding approvability in your meeting separately, regarding the statistical plan, there seems to be a concern about noninferiority on MACE, not MACE Plus, but MACE. Can you talk to your confidence around the statistics and whether that's an issue for the FDA? 27. Yu: In the FDA meeting, we have accomplished what we intended for the meeting. You asked about the important agreement or achievement. I will name that. We have gained FDA's agreement on our proposal for a single primary safety cardiovascular endpoint analysis for dialysis, as well as cardiovascular safety primary endpoint for nondialysis. And in terms of the way that the time to MACE primary endpoint is being analyzed in nondialysis, this will account for differential drop out between our drug and placebo, whereas you know that because placebo doesn't work in treating anemia, placebo patients had a tendency to	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
			drop out earlier. And we have reached agreement on statistical method that accounts for that. You have asked about our ***confidence on noninferiority on MACE***. At this time, with these understanding, ***level of confidence is very high***, and we do believe as AstraZeneca has stated that ***our Phase 3 results confirm cardiovascular safety of [R]oxadustat in the CKD population in both dialysis and non-dialysis***." *Id.* at 9. "Now, ***on the safety side– the ability to demonstrate a drug is as safe as placebo which is a very high bar***, because placebo is considered to give the drug an opportunity to show how safe it is based on its own merit." *Id.* at 12-13.		
28	169-170	**Speaker(s)**: FibroGen, Neff (CEO),Cotroneo (CFO) **Date**: August 8, 2019 **Occasion**: Form 10-Q for Q2 2019 **(Exhibit O)**	28. "In our pre-NDA meeting with the FDA, we ***reached agreement on the content to be included in our NDA submission package for Roxadustat for treatment of anemia in CKD, including the cardiovascular safety analyses for both CKD-dialysis and CKD-non-dialysis.*** The agreement for non-dialysis is an approach to account for the differential dropout between roxadustat and placebo observed in our Phase 3 studies. ***We are confident we have sufficient data for FDA review of our NDA in both CKD dialysis and CKD non-dialysis*** and we are planning to submit the NDA in October of 2019."	• Safety Analysis Statement • Efficacy Statement • Miscellaneous Statement	• Falsity Not Pled with Particularity • Statement of Corporate Optimism • Opinion
29	171-175	**Speaker(s)**: FibroGen **Date**: November 8, 2019 **Occasion**: Press release announcing	29. ***"Roxadustat cardiovascular safety comparable to placebo in [NDD] patients*** as assessed by [MACE] and MACE+"; (ii) "Roxadustat ***did not increase risk of MACE and reduced risk of MACE+ compared to epoetin alfa in [DD] patients"***; and (iii) "Roxadustat ***reduced risk of MACE by 30% and MACE+ by34% compared to epoetin alfa*** in the incident dialysis (ID) patient subgroup of the DD population."	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
		"Positive Phase 3 Pooled Roxadustat Safety and Efficacy Results" that had been presented at ASN Kidney Week 2019 ("ASN 2019 Press Release") **(Exhibit P)**			
30			30. In the press release, FibroGen reported a MACE hazard ratio of 0.96 (95% confidence interval, 0.82 to an upper bound of 1.13) for DD patients; a MACE hazard ratio of 1.08 (95% confidence interval, 0.94 to an upper boundof 1.24) in NDD patients; and a MACE hazard ratio of 0.70 (95% confidence interval, 0.51 to an upper bound of 0.96) in the incident dialysis sub-group of DD patients.	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement
31			31. Dr. Robert Provenzano, MD, Associate Professor of Medicine at Wayne State University and primary investigator of the global Phase 3 program stated: "The pooled safety analyses assessing Roxadustat as a treatment for anemia in chronic kidney disease demonstrate a cardiovascular safety profile ***comparable with placebo in patients not on dialysis*** and ***comparableor in some cases better than thatof epoetina alfa in patients on dialysis."***	• Safety Analysis Statement	• Falsity Not Pled with Particularity • No Defendant Alleged to Have Made Statement • Opinion Statement
32			32. "In the [NDD] patient population: ***Risks of MACE, MACE+, and all-cause mortality in Roxadustat patients were comparable to placebo in theITT analyses based on a reference non-inferiority margin of 1.3…ITT analysis agreed with the FDA.***	• Non-Inferiority Margin Statement • Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
			. . . In the [DD] patient population: ***Risks of MACE and all-cause mortality in [R]oxadustat patients were not increased compared to those for patients receiving epoetin alfa based on a reference non- inferiority margin of 1.3. Risk of MACE+ was 14% lower in Roxadustat-treated patients than in those receiving epoetin alfa."*** . . . The incident dialysis patient sub-group of the [DD] patient population: ***Risk of MACE was 30% lower in Roxadustat patients than in epoetin alfa patients, and risk of MACE+ was 34% lower."***		
33	177-178, 182-183	**Speaker(s)**: FibroGen, Schoeneck (Int. CEO), Yu (CMO) **Date**: November11, 2019 **Occasion**:3Q 2019 Earnings Call **(Exhibit R)**	33. Schoeneck: "The pooled results show that roxadustat's ***cardiovascular safety was comparable to placebo in [NDD] patients***. And ***in [DD] patients, roxadustat did not increase the risk of MACE and reduce the risk of MACE+ compared to epotin alfa,*** the leading product currently used to treat this population. Finally, in the subgroup of dialysis patients who recently started dialysis, referred to as ***incident dialysis patients, roxadustat reduced MACE by 30% and MACE+ by 34% compared to epoetin alfa.*** Roxadustat achieved the primary hemoglobin efficacy endpoitns in all of these groups…Having an oral product with this safety and efficacy profile can offer patients with anemia or chronic kidney disease and their doctors a treatment unlike anything currently on the market in the U.S. or Europe."	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement
34			Analyst: "I would just like to understand, since there seems to be some investor concern about FDA agreements and FDA sign-off…how your general impression was of your meeting with the FDA" 34. Yu: "First of all, I wanted to share that we have been in dialogue with the FDA in the past 6 years. And there has been a very good understanding about what the Phase III required study would look like and including the size of the study, how to power it [for example]	• Non-Inferiority Margin • Miscellaneous	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism • Forward-Looking Statement (NDA prospects)

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
			what's the primary endpoint and we agree on time to meet at the primary endpoint, and that's how we power for the non-dialysis and the dialysis. And we've also had a very productive dialogue with the FDA on the analysis of cardiovascular safety as well as what the efficacy requirement needs to be for this submission. And the most recent conversation with the FDA was at the end of July. And we had sent it to the FDA, a fairly comprehensive briefing package and had a very productive meeting. And ***walking out of it, we felt that we had all the guidance from the FDA we needed to put together a winning submission."*** Analyst: "so you feel no issue or no real concern about the hazard ratios and the [upper bounds] and all the things that people are talking about? You look at diabetes program and things like that, there's – you're well within that. So you don't feel any concern about that?" Yu: "No, we have ***no concern about that.*** And Mike, as you know, that our regulatory assessment is not based on 1 criterion. But instead, it is based on totality of evidence such as efficacy, safety, what is the medical need. And so based on our discussions and the historical precedents in this therapeutic area and the various conversations we've had with the agency***, we are very comfortable with our data where it is now."*** *Id.*		○ Identified As Forward-Looking (Ex. R at 4) & Adequate Cautionary Language (Ex. S at 49, 50, 51, 52, 53, 54, 57, 58, 70, 71) ○ No Allegations of Actual Knowledge of Falsity
35			35. Analyst: "When are you going to talk about the …statistical analysis plan, including the non-inferiority margin. Is there any pre-planned FDA meeting in the coming weeks?" Yu: "So the answer to that question is that we had already talked with the FDA about [the] analytical plan, and we had made the agreement on the analysis plan. The results that we have presented in the high-impact clinical session at the ASN, and ***the numbers I had just presented, were based on the agreed upon analysis plan that we have made with the FDA . . .***	• Non-Inferiority Margin • Miscellaneous Statement	• Falsity Not Pled with Particularity • Opinion Statement

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
			So we are talking about the analysis plan, meaning how do you pool, what's the pooling strategy and the analysis plan, how to analyze the data. When you talk about NI margins, you're talking about the standard for assessment, right? And as I mentioned earlier, that we expect that [all] regulators will assess the data based on the very -- all the -- on the entire application of the NDA. And based on our dialogue with the FDA over the past 6 years and the data, as we have shown, we are confident that we do have what it takes for this drug to be favorably evaluated."		
36	179, 182-183	Speaker(s): FibroGen Date: November14, 2019 Occasion: Email to Buyers Strike, theauthor of a November12, 2019 short report **(Exhibit T)**	36. "FGEN said in an emailed statement 'We do not agree with this report, which contains many inaccuracies. ***The data presented at [ASN] reflect the analytical methods and study pools agreed upon with the FDA***.'"	• Miscellaneous Statement	• Falsity Not Pled with Particularity • No Defendant Alleged to Have Made Statement
37	181-183	Speaker(s): FibroGen, Schoeneck (Int. CEO), Cotroneo (former CFO) Date: November12, 2019 Occasion: Form 10-Q for Q3	37. "The below ***cardiovascular safety analysis reflects the pooling strategy and analytical approach we agreed on with the FDA***. Similar sets of analyses will be submitted to the EMA to serve as the basis for potential approval in dialysis and non-dialysis in Europe, and additional supportive analyses and sensitivity analyses as well as subgroup analyses will also be included in the NDA and MAA. However, the FDA and EMA will each conduct their own benefit-risk analysis and may use additional statistical analyses other than those agreed with the FDA or set forth below, including, but not limited to, pre-specified or other analyses that may not sufficiently address the	• Safety Analysis Statement • Miscellaneous Statement	• Falsity Not Pled with Particularity

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
		2019 **(Exhibit S)**	differential drop-out rate between the roxadustat and placebo study arms in non-dialysis." *Id.* at 28.		
38			38. "In our pre-NDA meeting, the ***FDA agreed that the ITT- analysis would be our primary cardiovascular safety analysis method for non-dialysis in the U.S***. as it uses on-treatment and post-treatment long term follow-up (until a common study end date) to account for the higher drop-out rate in the placebo arm.***The figure below shows that in the 4,270 pooled non-dialysis patients (OLYMPUS, ANDES, and ALPS), the risk of MACE, MACE+, and all-cause mortality in Roxadustat patientswere comparable to that in placebo patients based on a reference non-inferiority margin of 1.3."*** *Id.*	• Non-Inferiority Margin Statement • Safety Analysis Statement • Miscellaneous Statement	• Falsity Not Pled with Particularity • Opinion Statement
39	184-186	Speaker(s): FibroGen, Conterno (CEO) Date: February25, 2020 Occasion:SVB Leerink Global Healthcare Conference **(Exhibit U)**	39. Conterno: "And then, of course, there is this question of, well, how does the cardiovascular safety look like. As you're aware, I've had a chance to conduct and be part of a number of cardiovascular studies in my previous role, and I believe that ***the data that we have on cardiovascular safety is very compelling***." *Id.* at 8.	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism
40			40. Conterno: "And ***when we look at the data, basically – we basically show to be comparable to placebo***. And importantly, when we look at the subcomponents of MACE, we had, or course, MI and stroke, and death, and…Hospitalization for heart failure and hospitalization for unstable angina. We – when we look at all those, in each – for each one of the	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
			subcomponents, that confidence interval actually encompassed one which makes ***our data extremely clean … from my perspective when it comes to cardiovascularsafety***." *Id.* at 8.		
41			41. Conterno: "There are not many options, and ***we have a trial that, in my view, basically, shows safety against what I think is a very high hurdle of placebo***." *Id.* at 9.	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement
42			42. Conterno: "And then, I think if you look at the data on its face, ***I do not believe that the data warrants a black box.*** Now there's a lot of context when we discuss a black box, and of course, there's a black box for EPO agents in the class. I get that, and the FDA takes many considerations. But I do think that it is a pretty high standard, and I'm ***very excited and delighted with the results that we got*** in -- ***out of cardiovascular safety . . .*** Yes. I think of -- it is the base case is, yes, that we have a broad label. And I think the base case for me is also that we get a black box, but we have the optionality of an upside of not be able to get one, given the data that we have. But that is an upside, I think, to our current plans. We can be extremely successful. This would be a transformational medicine, regardless."	• Safety Analysis Statement • Black Box Statement	• Forward-Looking Statement ("do not believe that the data warrants") ○ No Allegations of Actual Knowledge of Falsity • Falsity Not Pled with Particularity • Statement of Corporate Optimism • Opinion Statement
43			43. Conterno: "Keep in mind that the guidance that the FDA has provided is strictly for diabetes medicines, and the guidance for diabetes medicines is a ***1.3 upper bound***. So that means to -- we want to make sure – the FDA wants to make sure that products can exclude more than 30% risk of MACE events -- increased risk of MACE events. There is no such guidance for CKD anemia, which means that the FDA will have a -- this will become a product review issue when they look at the benefit/risk profile of the product. Now in our trial, ***when we looked at the pooled analysis***	• Non-Inferiority Margin Statement • Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
			of [NDD studies] ***we do basically see hazard ratios, about 1—slightly higher than 1, but the upper bound in each one of these cases, is below1.3.*** I do want to make the point the 1.3 number is an arbitrary number, okay? It was arbitrary for diabetes, and it's just a number. So at the end, I think it's a question of looking at what are the options. Keep in mind that the option today for those patients in NDD is really the EPOs actually have a black box and actually had a demonstration of -- sorry, a further trial." *Id.*		
44	187-188	Speaker(s): FibroGen, Yu (CMO) Date: March 2, 2020 Occasion: 4Q and FY2019 Earnings Call **(Exhibit V)**	44. Yu: "With ***the robust efficacy and safety profile demonstrated*** in our large Phase III program of over 8,000 patients, we believe roxadustat can potentially better address CKD anemia than what is currently available to CKD patients on dialysis and those not on dialysis. . . . Roxadustat-treated patients had ***lower transfusion risk than epoetin alfa patients, while lowering MACE+ risk in the dialysis patient pool.*** Notably, unlike ESA, Roxadustat maintain efficacy without increasing dose requirements in the presence of inflammation. . . . "Within the dialysis patient population, we are ***particularly excited about the cardiovascular safety results of the incident dialysis population.*** These patients entered the study during the first 4 months of dialysis initiation and had an average treatment duration of 1.5 years. We enrolled over 1,500 incident dialysis patients in this program, the largest in this population ever conducted. Here, we ***demonstrated a meaningful reduction in cardiovascular safety risk, as Roxadustat- treated incident dialysis patients had a 30% lower MACE risk and a 34% lower MACE+ than epoetin alfa-treated patients.*** We believe the high-risk incident dialysis population is the right and most appropriate setting for comparison of Roxadustat versus the epoetin alfa, since most patients are ESA-	• Efficacy Statement • Safety Analysis Statement	• Falsity Not Pled with Particularity • Forward-Looking Statement ("we believe") ○ Identified As Forward-Looking (Ex. V at 4) & Adequate Cautionary Language (Ex. W at 48, 50, 51, 54, 65, 66) ○ No Allegations of Actual Knowledge of Falsity • Opinion Statement • Statement of Corporate Optimism

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
			naïve to prior to study entry." *Id.* . . . ***With respect to cardiovascular safety, Roxadustat was comparable to placebo in risk of MACE and MACE+,*** while achieved a mean hemoglobin level of 11 grams per deciliter. . . . [Analyst: "And then on roxa, my question is, there is, obviously, some competitors around you, one of which will have Phase III data coming up shortly. Maybe you could comment on what we should keep in mind or what you're looking for and how to put that into context?"] . . . Now, however, I could comment on the Phase III study design, that we have designed a program to demonstrate safety in comparison to placebo and with the hope and ***confidence of gaining clean safety label fornon-dialysis***." *Id.* at 11.		
45	187-188	**Speaker(s)**: FibroGen, Conterno (CEO) and Cotroneo (CFO) **Date**: March 2, 2020 **Occasion**: 2019 Form10-K **(Exhibit W)**	45. *Non-Dialysis - Pooled Cardiovascular Safety Data* "In our pre-NDA meeting, the FDA agreed that the intent-to-treat analyses followed for long-term safety results would be our primary cardiovascular safety analysis method for non-dialysis in the U.S. as it uses on-treatment and post treatment long term follow-up (until a common study end date) to account for the higher drop-out rate in the placebo arm. The figure below shows that in the 4,270 pooled non-dialysis patients (OLYMPUS, ANDES, and ALPS), the risk of MACE, MACE+, and all-cause mortality in roxadustat patients were comparable to that in placebo patients based on a reference non-inferiority margin of 1.3." *Id.* at 9. *Dialysis - Pooled Cardiovascular Safety Data* "In the pooled on-treatment analysis of 3,880 dialysis patients (HIMALAYAS, SIERRAS, and ROCKIES), the risk of MACE and all-cause mortality in roxadustat patients were not increased (based on a reference non-inferiority margin of 1.3), and roxadustat lowered the	• Safety Analysis Statement • Miscellaneous Statement	• Falsity Not Pled with Particularity • Opinion Statement

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
			risk of MACE+ by 14% compared to the active comparator epoetin alfa, based on a hazard ratio of 0.86 and an upper bound of 95% CI under 1.0. The hazard ratios represent a point estimate of relative risk." *Id.* *Incident Dialysis Subgroup - Pooled Cardiovascular Safety Data* "In this program, incident dialysis patients are those who started participation in roxadustat Phase 3 studies within their first four months of dialysis initiation. In this clinically important subgroup of 1,526 incident dialysis patients, roxadustat reduced the risk of MACE by 30% and MACE+ by 34%, with a trend towards lower all-cause mortality. The lower MACE and MACE+ risks (compared to epoetin alfa) are based on hazard ratios of 0.70 and 0.66, respectively, with the upper bound of 95% CI under 1.0 in both. We believe this incident dialysis subpopulation is the appropriate setting for comparison of roxadustat versus epoetin alfa since most incident dialysis patients were ESA-naïve or have had only limited exposure to ESAs prior to study entry. In addition, the initiation of anemia therapy in this incident dialysis subgroup resembles clinical practice as the vast majority of US patients start anemia therapy early in dialysis treatment (during the first four months of treatment)." *Id.* at 10.		
46	189, 191	**Speaker(s)**: FibroGen, Yu (CMO) **Date**: May 7, 2020 **Occasion**:1Q 2020 Earnings Call	46. Yu: "Importantly, ***we have demonstrated cardiovascular safety in the overall dialysis population and in MACE***. And furthermore, we demonstrated a reduction in MACE+ risk. In our 1,530-incident dialysis patient pool, where the comparison between Roxadustatwith epoetin alpha started within the first 4 months of dialysis initiation, ***Roxadustat had a 30% lower risk of MACE and 34% lower risk of MACE+ than epoetin alfa, with a trend towards lower or cause mortality, relative to epoetinalfa***." *Id.* at 10.	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement
47			47. Yu: "When we look at the converted patients or the stable dialysis patients and evaluate and **looking at**	• Efficacy Statement • Safety Analysis	• Falsity Not Pled with Particularity

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
		(Exhibit X)	**safety -- *cardiovascular safety, it does not change any of the conclusions that we have on the -- about Roxadustat being safe and efficacious.*"** *Id.* at 11.	Statement	• Opinion Statement
48			48. Yu: "And so I also wanted to point out that placebo comparator offers as a comparator is a high bar for comparison for cardiovascular safety because, if one were to choose ESA, that -- as an agent, that already has a box warning for cardiovascular safety. But ***placebo is the gold standard. With -- in comparison to placebo, we have demonstrated that cardiovascular safety in the MACE endpoint and MACE+ endpoint.*"** *Id.* at 17.	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement
49			49. Yu: "And so, ***in conclusion, Roxadustat, excellent cardiovascular safetyprofile***, coupled with the statistically significant and clinically meaningful, higher hemoglobin efficacy results and ***lower transfusion rate relative to epoetin alfa,*** together makes Roxadustat potentially a ***better treatment option*** for dialysis-dependent patients. ***We like thehand that we have and expect the product label to reflect the results of clinical trials*** on our compound." *Id.* at 11.	• Safety Analysis Statement • Non-Inferiority Margin Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism • Forward-Looking Statement ("expect") o Identified As Forward-Looking (Ex. X at 4) & Adequate Cautionary Language (Ex. W at 48, 50, 51, 54, 65, 66) o No Allegations of Actual Knowledge of Falsity
50	190-191	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: May 14,	50. Conterno: "But in particular, as I think about the differentiation of Roxa, number one, I think you have to start with efficacy. Keep in mind that not only do we meet our primary efficacy end points, we were basically statistically superior to EPO on our trials in DD. So that's important. Of course, we also show efficacy. It was relative to placebo in NDD. And quite -- when we look at – one of the benefits of having achieved efficacy when it comes to hemoglobin is that	• Efficacy Statement • Safety Analysis Statement	• Falsity Not Pled with Particularity • Statement of Corporate Optimism • Opinion Statement

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
		2020 **Occasion**: Bank of America Securities 2020 HealthCare Conference **(Exhibit Y)**	it translates into lower transfusion rates. ***We actually had lower transfusions with Roxa than with EPO,*** and of course, much lower relative to placebo in the NDD segment. ***So that benefit to me, I think, is pretty significant***. Clearly, in the— when we look at the totality of the data, ***I find our overall cardiovascular data pretty compellin***g. And in particular, I think ***we need to highlight the incident dialysis data, whereby we basically show a reduction in risk of MACE events at a time that is critical***. And this is—incident dialysis, basically, covers those patients within the first 4 months of starting dialysis. That is the time when a treatment decision is made whenit comes to anemia. So I feel like we are perfectly accurate to wish -- with a huge benefit in that cohort of patients, to be able to have a significant position longer term in that segmentSo that I find also quite meaningful. Andclearly the data is highly—it was—***compared to EPO, it's highly differentiated based on what we can see.***" *Id.* at 6.		
51	192, 194	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: June 2, 2020 **Occasion**: Jefferies2020 Healthcare Conference **(Exhibit Z)**	51. Conterno: "I think in NDD we basically have a comparison relative to placebo. And therefore when we look at our data, ***I feel it basically shows that the product is safe because of the safety profile when it comes to CV comparable to placebo.*** In DD, yes, the question could be raised, well, you're comparing yourself to a product that has a black box in DD, and I get that. But in DD, ***when it comes to incident dialysis, we do show an actual significant benefit, well, with a 30% reduction in MAC***E . When I put those two reasons together, ***I look at the compelling nature ofour data, and I feel that the data does not warrant a BlackBox*** related to CV safety." *Id.* at 4.	• Safety Analysis Statement • Black Box Statement	• Falsity Not Pled with Particularity • Forward-Looking Statement ("data does not warrant") ○ No Allegations of Actual Knowledge of Falsity • Opinion Statement • Statement of Corporate Optimism
52	193-194	**Speaker(s)**: FibroGen, Conterno (CEO)	52 Conterno: ***"Importantly, CV safety was demonstrated across all studied populations. Non-dialysis- dependent, incident dialysis and dialysis dependent... In incidentdialysis patients, Roxadustat reduced risk of major adverse cardiovascular events***	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
		Date: June 4, 2020 **Occasion**: 2020 Annual Shareholder Meeting **(Exhibit AA)**	***or MACEby 30%***. And reduce[d] the risk of MACE+ by 34% compared to epoetin alfa. ***Both results were statistically significant***. There was also a trend towards lower all-cause mortality relative to epoetin alfa. Roxadustat clearly provides a large clinical benefit in the incident dialysis patient population, and we believe this is a natural decision point for health care professional[s] whenselecting which therapeutic agent will be utilized in the treatment of anemia." *Id.* at 7.		
53	195-197	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: June 9, 2020 **Occasion**: Goldman Sachs 41st Annual Global Healthcare Conference **(Exhibit BB)**	53. Conterno: "I think as you know, I've been very excited about our incident dialysis data and ***the fact that weshowed a 30% reduction in MACE risk and 34% when it comes to MACE plus. Honestly, that's huge and that's an anchor***. Because as patients start dialysis, clearly part of that dialysis initiation is going to betreatment of anemia. And I believe that ***we have the very best data. It's quite compelling and differentiated."*** *Id.* at 6.	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement
54			54. Conterno: "So as you said, I think we ***showed a significant benefit when it comes to MACE in [the incident dialysis] population, 30% reduction in MACE.*** Just for your audience, incident dialysis is basically we enroll patients that basically were starting dialysis…And what we –as you know, these patients are at significant risk because of the transition. It is one of the risker times for patients. And I think the results are quite compelling. Unfortunately, as you know survival with dialysis is not good…so giving them the best chance by whenever they start dialysis to have – to basically be on a treatment that has such compelling MACE results, I think is incredibly important. So I feel it is the natural point when the treatment decision for anemia will be made starting dialysis and where we have ***probably the most compelling data that we have.*** . . . And relative to EPO in DD, in incident dialysis where there are so many risks for CV events, we basically have a 30% reduction in MACE. That's an ***unbelievable***	• Safety Analysis Statement • Black Box Statement	• Falsity Not Pled with Particularity • Statement of Corporate Optimism • Opinion Statement

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
			result. So I find the data very compelling, and I don't believe the CV data -- safety data warrants a black box." *Id.* at 8.		
55			55. Conterno: "But I – as you know, there's a difference in trial design [in NDD] in that we compare [ourself] to placebo, which I think gives us ***the very best chance basically to have a label without a black box, given that we showed basically comparable safety to placebo.*** It is ***very difficult to achieve*** that -- if the trial is designed with a comparator relative to a product that has a black box." *Id.* at 7.	• Black Box Statement	• Falsity Not Pled with Particularity • Forward-Looking ("best chance . . . to have a label") • No Allegations of Actual Knowledge of Falsity • Opinion Statement

56	198, 200	**Speaker(s)**: FibroGen, Conterno (CEO)
		Date: August 6, 2020
		Occasion: 2Q 2020 Earnings Call **(Exhibit CC)**
			56. Conterno: "As it relates to a boxed warning, as I mentioned, we're not planning to make comments when it comes to labeling going forward. But clearly, ***we view that Roxadustat will be successful*** -- I think I've mentioned this to youand others in the past, ***very successful regardless.*** Clearly, we need to look at the entire label. And when we look at the label for Roxadustat, including a potential boxed warning, it's going to be what does the lab[el][5] in totality says and our ability to fully commercialize Roxadustat, given all the benefit that it can provide. ***We continue to view that our data shows a very positive benefit- risk profile for the product."*** *Id.* at 7.	• Black Box Statement
				• Safety Analysis Statement
				• Efficacy Statement
					• Falsity Not Pled with Particularity
					• Opinion Statement
					• Statement of Corporate Optimism
					• Forward-Looking Statement ("will be")
					  ○ Identified As Forward-Looking (Ex. CC at 4) & Adequate Cautionary Language (Ex. W at 48, 50, 51, 54, 65, 66)
					  ○ No Allegations of Actual Knowledge of Falsity

57			Analyst: "[W]hat are sort of the key takeaways …from your mid-cycle review meeting" and "what are the key …gating steps for you as you get to the end of the year on the review?" 57. Conterno: "[T]he mid-cycle review is an overall update of our submission. But when it comes to news,	• Miscellaneous Statement	• Falsity Not Pled with Particularity • Statement of Corporate Optimism • Opinion Statement

[5] The transcript of this earning call states "labor." However, in the recording of the earnings call, Conterno clearly states "label."

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
			as we've shared, the FDA indicated to us that there's no outcome that is planned at this stage. Clearly, you are asking about other types of interaction with the FDA going forward. I think it should be no surprise, but clearly, labeling discussions are critical, and those will be starting soon. And of course, we need preapproval inspections and so forth. But ***our engagement and our interaction with the FDA was positive. So we feel good aboutthe progress that we are making."*** *Id.* at 7-8.		
58	199-200	**Speaker(s)**: FibroGen, Conterno (CEO), Cotroneo (CFO) **Date**: August 6, 2020 **Occasion**:2Q 2020 Form 10-Q **(Exhibit DD)**	58. "As mentioned above, during the second quarter of 2019, ***the Company received positive topline results from analyses of pooled MACE and MACE+ data from its Phase 3 trials for Roxadustat, enabling the Company's NDA submission to the FDA***." *Id.* at 13.	• Safety Analysis Statement • Miscellaneous Statement	• Falsity Not Pled with Particularity • Opinion Statement
59	201, 203-204	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: September9, 2020 **Occasion**: Citigroup 15th	Analyst: "But let's begin with the topic that I think is probably at the top of a lot of investor's minds, and that's the vadadustat results that came out last week from Akebia in non-dialysis setting that seemed disappointing. But could you discuss your take on those results? And what that means for Roxadustat? 59. Conterno: **"**Yes, I think there are 3 elements that I would highlight as we think about those results and in the context for roxa. I think number one, I think is ***the significant level of evidence that we have already with Roxadustat around NDD.*** As you know, when we look at our pool studies for NDD, we were ***able to show non-***	• Non-Inferiority Margin Statement • Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
		Annual BioPharma Conference **(Exhibit EE)**	***inferiority relative to placebo, which is a higher bar than a comparison to a product that had – or product [that has] box warnings. So we feel very good about our pool MACE data in NDD."*** *Id.* at 5.		
60			Analyst: "I think a discussion that's come up a lot with investors, even before the data we saw last week is could roxadustat have a black box warning…Is it important to Roxadustat whether it has a black box warning or not?" 60. Conterno: "So we commented as part of the Q3 -- Q2 earnings call that unfortunately, given it was imminent that we would be entering labeling discussions that we were not going to be able to make further comments in terms of our engagement with the FDA. So that is the case. We feel --I think what I can say is ***we feel very good about where we are in terms of the review with the FDA,*** the level of engagement that we have. I know this question about a box warning comes often, which is are going to get one or not. My – and what is the impact that a box warning would have? It's always difficult to handicap what is going to be the final level. But we feel very good about the level of energy that we have. ***I think what I've said before is that we have excellent data. We don't believethat the data that we have warrants a box warning.*** But once again, difficult to handicap what we'll end up with the FDA." *Id.* at 6.	• Safety Analysis Statement • Black Box Statement • Miscellaneous Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism
61	202-204	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: September16, 2020 **Occasion**:	Analyst: "[H]ow do you think about roxa as different from vada, the Akebia product, given their recent non –NDD data?So do you look at that as…every drug is specific to its own targets? Or do you look at it as a mechanism effect, et cetera?" 61. Conterno: "Yes. Clearly, that's a question that is coming often to us, and I'll provide, I think, an appropriate perspective in terms of trying to put that result into context for investors. I'd like to make 3 points. Number one, Roxadustat has a very significant	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
		Morgan Stanley 18thAnnual Global Healthcare Conference **(Exhibit FF)**	data set in [N]DD. We have a pool analysis in NDD that we submitted to the FDA. As part of our NDD pool analysis, ***when we look at MACE, we were non-inferior relative to placebo, which is a higher bar than ESAs would be. So we feel very good about our data there***." *Id.* at 5.		
62	205-206	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: November5, 2020 **Occasion**:3Q 2020 Earnings Call **(Exhibit GG)**	62. Conterno: "Together with our partners, we had 42 presentations, including 10 oral, which add to the understanding of roxadustat's efficacy and safety profile and the unmet need -- and the unmet medical need in anemia of CKD. The roxadustat ***clinical data demonstrated consistent efficacy and reassuring safety results across the continuum of CKD patients with anemia***, adding to the established body of evidence highlighting roxadustat as a potential foundational treatment for this condition affecting millions of patients. We also presented data on the significant burden of anemia of CKD, a reminder that new treatment options for these patients are sorely needed." *Id.* at 5.	• Efficacy Statement • Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism

63			63. Conterno: "So we think [Roxadustat] ***has the right efficacy safety profile to be ableto have a really good uptake in the NDD setting and be able to be a catalyst for the overall expansion of that market.***" *Id.* at 10.	• Efficacy Statement
				• Safety Analysis Statement
					• Falsity Not Pled with Particularity
					• Forward-Looking Statement (roxadustat potential)
					  ○ Identified As Forward-Looking (Ex. GG at 4) & Adequate Cautionary Language (Ex. W at 48, 50, 51, 54, 65, 66)
					  ○ No Allegations of Actual Knowledge of Falsity
					• Opinion Statement
					• Statement of Corporate Optimism

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
64			64. Conterno: "Now when it comes to Roxa, I think what's important is when – first, when we look at the overall trial, we basically see that in ***NDD, we were comparable to placebo. So that's when it comes to MACE. So that's critically important. We showed non-inferiority."*** *Id.* at 14.	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement
65			65. Conterno: "So we think that roxadustat offers a number of benefits. I think if we think about straight off the bat, in incident dialysis, ***the excellent data that we have with – showing basically reduced cardiovascular outcomes in this population***, ***so that's extremely important."*** *Id.* at 12.	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Statement of Corporate Optimism • Opinion Statement
66	207, 209	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: November17, 2020 **Occasion**: Stifel 2020 Virtual Healthcare Conference **(Exhibit HH)**	Analyst: "I think The Street by now has accepted there'll be no AdCom. I still get the question. It's a disease area that's obviously been fraught with a lot of post-approval safety issues with a new class. So help us understand …what the FDA's reasoning here was for no FDA panel. I imagine they want to cover their bases, but just their comfort level with this space maybe is what got them here. So why don't you provide us some color around that?" 66. Conterno: "I can't speculate over why the FDA has not decided to have an AdCom or call an AdCom in this particular case…I typically think of the AdCom, it's just part of the process of the FDA approval. I don't see it as a negative or a positive in any way. And of course, given the chance of an AdCom, ***we had to prepare for one but that's really water under the bridge***. So at this stage, I think what I can say is basically we have to ***rely on the data that we've shared.*** And I feel that ***thedata that we shared,*** I think is ***very compelling when it comes to Roxadustat*** and the ability to basically show yes, improving, correcting and maintaining hemoglobin levels, but importantly, as a result, decreasing the number of transfusions and then the broad safety data that we have first thing in DD, where we look at both our safety data there when we compared to ESAs. As you know ***we have had pretty compelling data when it comes to incident dialysis we***	• Safety Analysis Statement • Miscellaneous Statement	• Falsity Not Pled with Particularity • Statement of Corporate Optimism • Opinion Statement

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
			had stat[istical] sig[nificance] in terms of a reduction in the number of MACE events in thatsetting. And then when we look ***at NDD, we were compared to placebo and we basically had comparability when it comes to overall safety***. So, feel very goodabout the overall package that we had." *Id.* at 2. [Analyst: "What are [dialysis providers] going to be learning from the piloting of this product to gain additional experience, to get them comfortable? Are there certain metrics they're looking for?"] Conterno: **"**Keep in mind; whenever we conduct the Phase 3 trials, we are looking at the product from the perspective of evaluating the efficacy and the safety of the product from that perspective of FibroGen. ***Clearly, we've already said and have demonstrated both the efficacy and the safety of the product***. So, when it comes to the Phase 3 studies we are now working within each of the dialysis organizations to better assess basically this product within those specific settings, right." *Id.* at 7.		
67	208-209	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: November19, 2020 **Occasion**: Jefferies Virtual London Healthcare Conference **(Exhibit II)**	Analyst: "[A]s you get here towards the end of the PDUFA, what – or how will you help investors out, thinking about the 2 or 3 different scenarios. One of those scenarios is approval with a clean, very, very, very clean broad label. One of those scenarios is approval, but maybe it looks a little more like an EPO label and one of them could be a delay…But talk about those different scenarios And what are the implications of each of those?" 67. Conterno: "Yes. ***Clearly, we have a high level of conviction on the overall submission, the strength of our data***, so what I'm going to focus on is basically thinking about really the bookends of maybe what the label will look like. And on one hand, I think you have a label -- and I know there's a lot of focus on the box warning, but our label that doesn't have a box warning. On the other hand, you have basically, on the other bookend, a label that has a box warning that looks like the EPO box warning. There are, of course, a number	• Black Box Warning • Safety Analysis Statement • Miscellaneous Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism • Forward-Looking Statement ("what label *will look like*") ○ No Allegations of Actual Knowledge of Falsity

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
			of scenarios in between." *Id.* at 5-6.		
68			Analyst: "I've gotten a lot of investor questions about how it may not just be as simple as black box or no black box. Are you implying that if you go look at different classes, different black boxes, say different things, you could actually have comments in a black box only on a specific indication." 68. Conterno: "Yes. I think we need to wait, of course, for our particular scenario. I'm not implying that we will have that, but all of those are possibilities. ***Clearly, I think the -- when we look at our data, we continue to feel that the data basically offers a very favorable risk-benefit profile for patients across the continuum.*** Now one comment on any details at this stage. But yes, I think key is going to be for us, for us to look at the entire label, if there is a box warning, and that needs to be put into the context. And what is the rest of the label also say. So we of course, as you can imagine, we think about all scenarios from a planning perspective, and now we're prepared for all scenarios and prepared to execute." *Id.* at 6.	• Black Box Statement • Safety Analysis Statement • Miscellaneous Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism
69			69. Conterno: "So if we think about roxadustat, there -- if we just take -- look at the number of patients on dialysis, we have to start that there are a number of those patients in dialysis. Most of them are treated for anemia, but we have about 15%, 20% of those patients that are hyporesponsive, right? So where ESAs are not working very well. Roxadustat will be an excellent option there, okay? ***What about the incident dialysis population, where we basically showed a very significant benefit when it comes to MACE and MACE+.*** *Id.* at 7.	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism
70	211-215	**Speaker(s)**: FibroGen, Frost (Senior VP)	70. Frost: "***Cardiovascular safety of Roxadustat was also carefully evaluated, and demonstrated in the Phase 3 program,*** by assessment of major adverse cardiovascular events (MACE) from pooled analyses of	• Safety Analysis Statement	• Falsity Not Pled with Particularity • No Defendant Alleged to Have

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
		Date: December9, 2020 **Occasion**: Letter to theFDA	Phase 3 studies. In the MACE analysis ofthe DD-CKD patient pool, ***roxadustat demonstrated non-inferiority compared to epoetin-alfa, and in the NDD- CKD pool, Roxadustat demonstrated non-inferiority to placebo with respect to MACE.***"		Made Statement • Opinion Statement
71		Respondingto the Citizen Petition **(Exhibit KK)**	71. Frost: ***"FibroGen's NDA submission was complete, complied with all FDA guidance, and included data from all clinical and preclinical studies.*** The Integrated Summary of Safety cardiovascular safety report includes the pooled cardiovascular safety analyses of the DD-CKD, and NDD-CKD patient populations. In addition, for completeness and full transparency, FibroGen includedcertain cardiovascular safety sensitivity analyses, including the stable dialysis subgroup, and the DD-CKD pool including the PYRENEES study. ***The results from these sensitivity analyses do not change the conclusions with respect to MACE of non- inferiority of roxadustat to epoetin-alfa in DD-CKD patients, and non-inferiority of roxadustat to placebo in NDD- CKD patients. In conclusion, FibroGen's NDA submission was complete and transparent. The data supporting the safety and effectiveness of roxadustat is robust and compelling."*** *Id.* at 2.	• Safety Analysis Statement • Miscellaneous Statement	• Falsity Not Pled with Particularity • No Defendant Alleged to Have Made Statement • Opinion Statement • Statement of Corporate Optimism
72	217, 220	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: March 1, 2021 **Occasion**: Press release announcingthat the FDA would	72. Conterno: "While disappointed with the news today, FibroGen and AstraZeneca are committed to working with the FDA to bring Roxadustat to patients with anemia of CKD in the U.S. as soon as possible…***We continue to be confident in the efficacy and safety profile of this new potential medicine based on positive results from aglobal Phase 3 program encompassing more than 8,000patients."***	• Efficacy Statement • Safety Analysis Statement • Miscellaneous Statement	• Falsity Not Pled with Particularity • Opinion Statement

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
		hold an AdCom meeting **(Exhibit LL)**			
73	218, 220	**Speaker(s)**: FibroGen, Conterno (CEO), Eisner (CMO) **Date**: March 1, 2021 **Occasion**: 4Q and FY2020 Earnings Call **(Exhibit MM)**	73. Eisner: "***We continue to have confidence in the completeness of our NDA submission, the strength of our data***, and along with our partner, AstraZeneca, we're committed to working together with the FDA to bring Roxadustat to patients with anemia of CKD in the U.S." *Id.* at 8. "I mean, to address the specifics of your timing, yes, it's a little late in the game under -- in the review process to get a request for an advisory committee, but the FDA is well within its rights and regulations to request an advisory committee at any time. And we're very willing and able to have this discussion in public and present our data, which, as we alluded tobefore, ***we're quite confident in.***" *Id.* at 10.	• Miscellaneous Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism
74			74. Conterno: "Clearly, I won't be sharing what are we planning to present and so far, but you can imagine, ***the data that we have on incident dialysis, we believe, is some of our strongest*** data***. As we think about MACE and MACE+ significance in that population. So clearly, very, very important data.***" *Id.* at 13.	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism
75	219-220	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: March 2, 2021 **Occasion**: 41st Annual	75. Conterno: "It is not unusual for the FDA to hold an Adcom for a first-in-class new molecular entity. And in fact, we shared last spring that we were preparing for -- very much for that possibility. So now I think for us, we are refocusing our efforts on resuming those activities. I'm very much looking forward now to presenting the comprehensive roxadustat data in that public [setting]. We continue to have confidencein ***the completeness of the NDA submission and the strength of the roxadustat data.***" *Id.* at 5.	• Miscellaneous Statement	• Falsity Not Pled with Particularity • Statement of Corporate Optimism • Opinion Statement
76			76. Conterno: "But at the end, I think we know that an Adcom is an opportunity to basically showcase, I	• Safety Analysis Statement	• Falsity Not Pled with Particularity

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
		Cowen Healthcare Conference **(Exhibit OO)**	think, the***strength of our data***, and we continue to have ***confidence on the strength of the data of Roxadustat across both DD and NDD."*** *Id.* at 6.	• Miscellaneous Statement	• Statement of Corporate Optimism • Opinion Statement
77			77. Conterno: "Honestly, I think we feel highly confident about both DD and NDD. We think that the data, I think, ***supports -- the benefit risk profile***." *Id.* at 8.	• Safety Analysis Statement • Miscellaneous Statement	• Falsity Not Pled with Particularity • Statement of Corporate Optimism • Opinion Statement
78			78. Conterno: "I know because we've discussed in the past, and I think ***I've been pretty clear in terms ofwhat has been agreed with the FDA and what hasn't been agreed with FDA. I think that's known***." *Id.* at 8.	• Miscellaneous Statement	• Falsity Not Pled with Particularity
79	222, 227-229	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: April 6, 2021 **Occasion**: Press release announcing that the primary cardiovascular safety analyses included post-hoc changes to the stratification factors.	79. Conterno: "It is important to emphasize that ***this does not impact our conclusion regarding the comparability, with respect to cardiovascular safety, of Roxadustat to [Epogen] in dialysis-dependent(DD) patients and to placebo in non-dialysis dependent (NDD) patients."***	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement
80			80. Conterno: "***We continue to have confidence in Roxadustat's benefit risk profile***."	• Safety Analysis Statement • Miscellaneous Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism
81			81. Press Release: "These analyses do not change the Company's assessment that ***Roxadustat is comparable to placebo in*** non***-dialysis dependent patients and to epoetin-alfa in dialysis dependent patients using MACE to measure cardiovascular safety***."	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
		(Exhibit PP)			
82	223-229	**Speaker(s)**: FibroGen, Conterno (CEO), Eisner (CMO) **Date**: April 6, 2021 **Occasion**: "Business Update Call" to Discuss Admissions **(Exhibit QQ)**	82. Conterno: "Our conclusion regarding ***the comparability with respect to cardiovascular safety of Roxadustat*** to ***epoetin-alfa in dialysis-dependent patients and to placebo in nondialysis- dependent patients is not impacted***. So let me be very clear. We continue to have ***confidence in Roxadustat's benefit risk profile, and we'recommitted to working closely with the FDA to bring this important new treatment to patients living with anemia of CKD.."*** *Id.* at 4.	• Safety Analysis Statement • Miscellaneous Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism
83			83. Eisner: "Importantly, these analyses do not change the Company's assessment that ***Roxadustat is comparable to placebo in*** nondialysis***- dependent patients and to epoetin-alfa in dialysis-dependent patients using MACE to measure cardiovascular safety***." *Id.* at 5.	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement
84			Analyst: Can you be clear whether the upper bound of the confidence intervals that was pre-agreed with the agency was 1.25 or 1.3 for noninferiority?... Do you still believe that are you are non-inferior to Placebo in non-dialysis setting?" 84. Conterno: "Yes, we continue to believe that ***in non- dialysis, we basically show comparability relative to placebo***. With regards to the 1 point to any measures of excess risk***, you mentioned 1.25 or 1.3, I think I said in a number of different occasions that we do not have a pre-agreed non- inferiority margin with the FDA.*** That has always been a – what we share as a review issue, an issue that needs to be looked at when the FDA looks at the totality of the efficacy and safety data for Roxadustat. When it comes to the NDA, we did submit a number of different analyses, including both sets of this analysis that we are sharing with you with the FDA." *Id*. at 7.	• Safety Analysis Statement • Non-Inferiority Margin Statement	• Falsity Not Pled with Particularity • Opinion Statement
85			85. Conterno: "But clearly, ***ourconclusions when it comes, as I***mentioned***, to -- in NDD and DD that we're comparable to placebo in NDD and comparable in***	• Safety Analysis Statement	• Falsity Not Pled with Particularity

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
			DD to EPO have not changed a from a safety perspective. I think that's a ***critically important message.*** When it comes to incident dialysis, the ***numbers continueto be quite positive***. But at this stage, I think for MACE, it crosses 1. So we can no longer make the conclusion that we have a statistically superior result when it comes to MACE relative to EPO in this specific population." *Id.* at 8.		• Opinion Statement
86			86. Eisner: "[T]he incident dialysis point estimates are still below 1. And the ***overall analysis are consistent with comparable*** safety ***to placebo in the NDD population and to ESA in the dialysis-dependent population.*** And overall, we feel ***very good about the overall benefit-risk profile of the drug.***" *Id.* at 9.	• Safety Analysis Statement • Miscellaneous Statement	• Falsity Not Pled with Particularity • Statement of Corporate Optimism • Opinion Statement
87			Analyst: "[A]s you think about the incremental changes, especially to the upper ends of the confidence interval, I guess how – what would your suggestion or what is the guidance here with regard to just thinking about the safety profile, given that the confidence intervals now are above 1 here." 87. Eisner: "So in the incident dialysis population, you're correct that the upper bounds for MACE and MACE+ now at 1. And for the dialysis-dependent population for MACE+, that's also true. But still, ***the overall results are very comparable in the NDD population to -- for Roxadustat to placebo and in the DD and the incident dialysis subpopulation, comparable to ESA's in terms of cardiovascular safety.*** So overall, we continue to believe that ***the benefit risk profile of Roxadustat is favorable***." *Id.* at 10.	• Safety Analysis Statement • Miscellaneous Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism
88			Analyst: "[D]o you believe that this – if you have to recommunicate this to the physician population, does this change their perception of the safety with regard to what they might want to use it in NDD population." 88. Eisner: "So you asked about specifically the non-	• Safety Analysis Statement • Miscellaneous Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
			dialysis dependent population and how we would communicate that to the physician community. And I think we can clearly state that ***the results with the prespecified stratification factors continue to support comparable cardiovascular safety between [R]oxadustat and placebo and a positive benefit risk profile***. So although we're now presenting you this information with the prespecified stratification factors, it's a very consistent message to the one that was communicated with the post-hoc stratification factors." *Id.* at 10.		• Optimism
89			89. Eisner: "We believe that the prespecified -- the analysis with the prespecified stratification factors is the primary analysis, which should be emphasized when it comes to the analysis of MACE in both NDD and DD populations. That said, it's always been the plan to provide a variety of sensitivity analyses and different approaches to look at the cardiovascular safety data that's supportive. So I do think that the Advisory Committee, during the FDA's review, they will take a totality of the evidence approach that takes a number of different analyses into account. At the end of the day, we do believe that ***the benefit/risk profile of roxadustat is positive and that the review will likely conclude that***." *Id.* at 13.	• Miscellaneous Statement	• Falsity Not Pled with Particularity • Forward-Looking Statement ("will likely") o Identified As Forward-Looking (Ex. QQ at 4) & Adequate Cautionary Language (Ex. NN at 3-4, 50-52, 55, 68, 69) o No Allegations of Actual Knowledge of Falsity • Statement of Corporate Optimism • Opinion Statement
90	230, 232	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: May 10, 2021 **Occasion**:Q1	90. Conterno: "Importantly, this clarification ***does not impact our overall conclusions regarding the comparability with respect to cardiovascular safety of Roxadustat to epoetin alfa in dialysis-dependent patients and to placebo in non-dialysis dependent patients***. As described on April 6, for the incident dialysis subgroup, based on the prespecified stratification factors, roxadustat is comparable but not superior to epoetin alfa with regards to cardiovascular safety."	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement
91			91. Conterno: "I want to reiterate thatwe continue to	• Miscellaneous	• Falsity Not Pled with

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
		2021 Earnings Call **(Exhibit RR)**	have ***confidence in the Roxadustat data and in the safety and efficacy profile demonstrated in the Phase 3 program."*** *Id.* at 5.	Statement • Safety Analysis Statement	Particularity • Opinion Statement • Statement of Corporate Optimism
92	231-232	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: May 13, 2021 **Occasion**: Bank of America Annual Healthcare Conference **(Exhibit SS)**	92. Conterno: And just to remind everyone, I think when we look at Roxadustat, we view it as ***comparable on both dialysis dependent and non-dialysis dependent comparable to ESAs on*** dialysis ***dependent onto placebo on non-dialysis dependent.*** And we have now, I think, the opportunity to -- so patients are starting those treatment with dialysis to be able to treat anemia. And we think that Roxadustat ***can be an ideal choice there given the strength of our data, in particular inincident dialysis***." *Id.* at 5.	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism
93			93. Conterno: "So I think it's -- at the end of the day, I think the world post TDAPA would be governed by how well did roxadustat perform within the 2-year period as assessed by CMS. I'm ***quite confident on what Roxadustat can deliver***. . . . And the -- when we look at our data, we have a number of different trials, both in DD and NDD. And then we need to look at the overall cardiovascular profile. And as I mentioned, we see our profile being, ***when it comes to MACE, noninferior to ESAs on DD and non-inferior comparable to placebo on NDD.*** . . . "at this point in time, of course, the FDA will look at the primary analysis, but I'm sure we will also do a number of additional sensitivity analysis and we – that I'm sure will be discussed. Those sensitivity analysis, in some cases, look – make the product – or hazard ratios lower, in some cases, higher. But all in all, I think, it should help understand, I think, the overall profile of the product better. And I'm optimistic about – ***given our preparation that we will have a good***	• Safety Analysis Statement • Efficacy Statement • Miscellaneous Statement	• Falsity Not Pled with Particularity • Opinion Statement • Statement of Corporate Optimism • Forward-Looking Statement ("can deliver"; "we will have a good showing") o No Allegations of Actual Knowledge of Falsity

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Alleged False and Misleading Statements[1]	Statement Category[2]	Reason Not Actionable (Falsity)[3]
			showing." *Id.* at 10.		
94	233, 235	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: June 4, 2021 **Occasion**: Jefferies Healthcare Conference **(Exhibit TT)**	94. Conterno: "Keep in mind, I think what -- and I think it's ***important that I highlight that Roxadustat has shown comparability when it comes to both placebo in NDD and relative to EPO in DD***." *Id.* at 4.	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement
95			95. Conterno: "And while we are -- when we look at the hazard ratio of – in incident dialysis, well, it is not below – while the upper bound is not below 1, the hazard ratio, the estimate is ***still below 1, and it looks very, very positive."*** *Id.* at 4.	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement
96	234-235	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: June 10, 2021 **Occasion**: Goldman Sachs 42ndAnnual Global Healthcare Conference **(Exhibit UU)**	96. Conterno: "Yes. I think what the data -- what the data shows is -- what the analogy shows is basically the ***Roxadustat is comparable to ESAs to EPO in the DD setting and comparable to placebo in the NDD setting***." *Id.* at 7.	• Safety Analysis Statement	• Falsity Not Pled with Particularity • Opinion Statement